



- **MHRA publishes summary of suspected adverse drug reactions to antiviral medications**

The MHRA has published a summary of all UK reports of suspected adverse drug reactions (ADRs) to oseltamivir and zanamivir received between 1st April 2009 and 13th August 2009.

These reports have been submitted voluntarily by healthcare professionals and members of the public via the Swine Flu ADR Portal and the Yellow Card Scheme. They also include those submitted by the Marketing Authorisation holders for Tamiflu and Relenza as part of their legal requirements.

The MHRA will produce a weekly summary each Thursday, which will include all side effects to Tamiflu and Relenza reported up to the end of the previous week. The headline summary from this first report is as follows.

- As of August 13 2009, the MHRA had received 533 reports for Tamiflu, mentioning 895 suspected ADRs
- For the same period there were 12 reports for Relenza, with 19 suspected ADRs
- No new safety concerns have been identified for either drug and there is no change to the product information. Patients should continue to take Tamiflu or Relenza as advised by their healthcare provider.
- The balance of risks and benefits for antivirals remains positive. The MHRA continues to closely monitor a number of potential safety signals for which an association with Tamiflu or Relenza has yet to be confirmed.

<http://www.mhra.gov.uk/Safetyinformation/Swinefluinformation/Antiviralmedicines/index.htm>

- **Treatment of Non-Tuberculous Mycobacteria in the Community**

The funding of the drugs used for treatment for Tuberculosis rests with the Acute Trusts and all the prescriptions are issued by the Chest Physicians. However, some drugs commonly used for TB are prescribed for patients with non-tuberculous infections and this has given rise to some confusion.

There are a large number of organisms that look like TB under the microscope. They are all very slow-growing so, if a patient is presenting with a clinical picture of TB and appropriate chest X-ray changes etc, it is reasonable to commence standard anti-tuberculous therapy for that patient. However, when the laboratory cultures the organism and identifies that it is not actually TB, the treatment has to be changed.

The non-tuberculous or "atypical" mycobacteria are resistant to several of the anti-TB drugs and are harder to eradicate than TB. Treatment is given according to BTS guidance and usually consists of 18 months of Rifampicin and Ethambutol. As they are not being used to treat tuberculosis, these prescriptions can be issued by GPs.

The TB Nurses are happy to help with any queries on 01536 494224.

- **Glitazones appear to increase fracture risk in men and women, pioglitazone possibly more so**

A prospective cohort study (Arch Intern Med 2009; 169: 1395-402) in patients with type 2 diabetes found that treatment with a thiazolidinedione (glitazone) increased fracture risk in both men and women; pioglitazone appeared to be associated with a greater risk than rosiglitazone.

Observational studies and analysis of clinical trial data (see below) have already indicated that treatment with a glitazone increase the risk of fractures in women, however the evidence is still uncertain especially in relation to effects on risk in men.

Compared to those treated with sulphonylureas, patients receiving a glitazone had an increased risk of peripheral fracture (HR, 1.28; 95% CI, 1.10 to 1.48) across the group. When the glitazones were examined separately in comparison to sulphonylureas, the risk with rosiglitazone for women was not significant (HR, 1.17; 95% CI, 0.91 to 1.50) whereas that for pioglitazone was (HR, 1.77; 95% CI, 1.32 to 2.38).

Overall fracture risk for men was not significantly different in the glitazone group (HR, 1.20; 95% CI, 0.96 to 1.50), however analysis by individual drug found no significant risk with rosiglitazone (HR, 1.00; 95% CI, 0.75 to 1.34) but a significant increase for pioglitazone (HR, 1.61; 95% CI, 1.18 to 2.20).

The authors conclude that their analysis further supports the association of glitazones with increased risk of fractures in women, and indicates a possible association between pioglitazone use and increased risk in men. Further research is needed to gain greater certainty.

A meta analysis of 10 RCTs (Loke YK, et al. CMAJ 2009;180:32-9) looking at glitazones and fracture risk estimated an NNH of 55 over 1 year for women with an average age of 56 years and recent diagnosis of diabetes; that is, for every 55 women treated with a glitazone for 1 year, one extra woman develops a fracture who would not have done had they not received a glitazone. Among older women the NNH was estimated as 31 at a mean age of 65 years, and 21 at a mean age of 72 years.

Health professionals should heed [MHRA warnings](#) and follow [NICE guidance](#), and not commence or continue a glitazone in people at higher risk of fractures, in addition to considering the [cardiovascular risks](#) of glitazones.

See <http://www.npci.org.uk/blog/?p=253> for a full summary.

This edition is also available on HNN (Health Network Northants)

<http://www.northants.nhs.uk/Display/Dynamic.jsp?topid=14070&lhsid=514&oid=2854¤tid=2854>

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